




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460


OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 6/25/2019

Subject: Efficacy Review for Tail, EPA Reg. No. 5813-REG
(DP Barcode: 451332, E-Submission: 36085)

From: Samantha Collins
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P) 

Thru: Kristen Willis, Branch Chief
Product Science Branch
Antimicrobials Division (7510P) 
Date Signed: 6/25/2019

To: Eric Miederhoff, Team 31 / Emilia Oiguenblik
Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: CLOROX CO.

Formulation from the Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	1.48%
Didecyl dimethyl ammonium chloride.....	0.555%
Octyl decyl dimethyl ammonium chloride	1.11%
Dioctyl dimethyl ammonium chloride.....	0.555%
<u>Other Ingredients</u>	96.3%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: New registration

Currently registered efficacy claim(s): None

Requested action(s): Add Laundry sanitization claims for cotton fabric at a 8-minute 50-second contact time for top loading washing applications and 15-minute 50-second contact time for High efficiency applications with no organic soil load present.

Documents considered in this review:

- Letter from applicant to EPA dated February 1, 2019
- Data Matrix (EPA Form 8570-35)
- 12 efficacy studies (MRID 50749705 - 50749716)
- Proposed label dated 1/4/2019
- Confidential Statement of Formula (EPA Form 8670-4) dated 12/27/2018.

II PROPOSED DIRECTIONS FOR USE

“To Sanitize: Add to rinse cycle and leave product in [contact -or- with articles -or- rinse cycle] for 16 min[utes].

For [H[igh] E[fficiency] -or- Front Load] Machines: Add 3.3 fl oz -or- 1 capful filled to level -or- line 2 [of the dosing cup] to the fabric softener compartment -or- drawer [of the washing machine] or directly to your rinse cycle wash. [If total amount does not fit, add the remaining amount into the compartment -or- drawer when rinse cycle wash begins.]

For [Standard -or- Top Load] Machines: Add 14.9 fl oz -or- 4 capfuls each filled to level -or- line 2 [of the dosing cup] and 1 capful filled to level -or- line 1 each to the fabric softener compartment -or- drawer [of the washing machine] or directly to your rinse cycle wash. [If total amount does not fit, add the remaining amount into the compartment -or- drawer when rinse cycle wash begins.]”

III STUDY SUMMARIES

1.	MRID	50749705	Study Completion Date:	11/14/18			
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26235					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Klebsiella pneumoniae (ATCC 4352)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18009					
	Preparation	Tested concentration: LCL Dilution: 7mL/993 mL (ratio 1:141.86) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	8 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:10 (weight/weight) for Top-loading Applications					

2.	MRID	50749706	Study Completion Date:	11/26/18			
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26234					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Klebsiella pneumoniae (ATCC 4352)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18010					
	Preparation	Tested concentration: LCL Dilution: 7mL/993 mL (ratio 1:141.86) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	8 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:10 (weight/weight) for Top-loading Applications					

3.	MRID	50749707	Study Completion Date:		11/26/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26229					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Klebsiella pneumoniae</i> (ATCC 4352)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18011					
	Preparation	Tested concentration: LCL Dilution: 7mL/993 mL (ratio 1:141.86) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	8 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:10 (weight/weight) for Top-loading Applications					

4.	MRID	50749708	Study Completion Date:		11/14/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26232					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Staphylococcus aureus</i> (ATCC 6538)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18009					
	Preparation	Tested concentration: LCL Dilution: 7mL/993 mL (ratio 1:141.86) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	8 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:10 (weight/weight) for Top-loading Applications					

5.	MRID	50749709	Study Completion Date:		11/14/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26233					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18010					
	Preparation	Tested concentration: LCL Dilution: 7mL/993 mL (ratio 1:141.86) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	8 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:10 (weight/weight) for Top-loading Applications					

6.	MRID	50749710	Study Completion Date:		11/14/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26231					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18011					
	Preparation	Tested concentration: LCL Dilution: 7mL/993 mL (ratio 1:141.86) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	8 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:10 (weight/weight) for Top-loading Applications					

7.	MRID	50749711	Study Completion Date:		11/20/18
Study Objective		Laundry Sanitizer			
Testing Lab; Lab Study ID		Accuratus; A26386			
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Klebsiella pneumoniae (ATCC 4352)			
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers			
Application Method		Liquid Concentrate			
Test Substance Preparation	Name/ID	Tail			
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18009			
	Preparation	Tested concentration: LCL Dilution: 8.5mL/991.5 mL (ratio 1:116.65) Diluent: 100 ppm AOAC synthetic hard water			
Soil load		N/A			
Carrier type, # per lot		Plain cotton weave			
Test conditions		Contact time	15 min 50 sec	Temp	20°C RH -
Neutralizer		D/E Neutralizing Broth			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:4.99 (weight/weight) for High Efficiency Applications			

8.	MRID	50749712	Study Completion Date:		11/20/18
Study Objective		Laundry Sanitizer			
Testing Lab; Lab Study ID		Accuratus; A26387			
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Klebsiella pneumoniae (ATCC 4352)			
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers			
Application Method		Liquid Concentrate			
Test Substance Preparation	Name/ID	Tail			
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18010			
	Preparation	Tested concentration: LCL Dilution: 8.5mL/991.5 mL (ratio 1:116.65) Diluent: 100 ppm AOAC synthetic hard water			
Soil load		N/A			
Carrier type, # per lot		Plain cotton weave			
Test conditions		Contact time	15 min 50 sec	Temp	20°C RH -
Neutralizer		D/E Neutralizing Broth			
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:4.99 (weight/weight) for High Efficiency Applications			

9.	MRID	50749713	Study Completion Date:		11/20/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26388					
Test organism(s)		Klebsiella pneumoniae (ATCC 4352)					
☑ 1 ☐ 2 ☐ 3 ☐ 4+							
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots	18011					
	☑ 1 ☐ 2 ☐ 3						
Preparation		Tested concentration: LCL Dilution: 8.5mL/991.5 mL (ratio 1:116.65) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	15 min 50 sec	Temp	20°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:4.99 (weight/weight) for High Efficiency Applications					

10.	MRID	50749714	Study Completion Date:		11/14/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26383					
Test organism(s)		Staphylococcus aureus (ATCC 6538)					
☑ 1 ☐ 2 ☐ 3 ☐ 4+							
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots	18009					
	☑ 1 ☐ 2 ☐ 3						
Preparation		Tested concentration: LCL Dilution: 8.5mL/991.5 mL (ratio 1:116.65) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	15 min 50 sec	Temp	21°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:4.99 (weight/weight) for High Efficiency Applications					

11.	MRID	50749715	Study Completion Date:		11/20/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26385					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18010					
	Preparation	Tested concentration: LCL Dilution: 8.5mL/991.5 mL (ratio 1:116.65) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	15 min 50 sec	Temp	21°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:4.99 (weight/weight) for High Efficiency Applications					

12.	MRID	50749716	Study Completion Date:		11/14/18		
Study Objective		Laundry Sanitizer					
Testing Lab; Lab Study ID		Accuratus; A26384					
Test organism(s) <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		Staphylococcus aureus (ATCC 6538)					
Test Method		Standard Test Method for the Evaluation of Laundry Sanitizers					
Application Method		Liquid Concentrate					
Test Substance Preparation	Name/ID	Tail					
	Lots <input checked="" type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	18011					
	Preparation	Tested concentration: LCL Dilution: 8.5mL/991.5 mL (ratio 1:116.65) Diluent: 100 ppm AOAC synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		Plain cotton weave					
Test conditions		Contact time	15 min 50 sec	Temp	21°C	RH	-
Neutralizer		D/E Neutralizing Broth					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Fabric/Test Substance Ratio: 1:4.99 (weight/weight) for High Efficiency Applications					

IV STUDY RESULTS

Laundry Sanitization Efficacy

MRID	Organism	Fabric/Test Substance Ratio	No. Exhibiting Growth/Total No. Tested			Carrier Control Geometric Mean (Average Log ₁₀)
			Batch 18009	Batch 18010	Batch 18011	
8-minute 50-second contact time, 100 ppm hard water, no soil load, 1:141.86 dilution ratio						
50749705 50749706 50749707	Klebsiella pneumoniae (ATCC 4352)	1:10 (weight/weight) for Top-loading Applications	99.9%	99.99%	>99.99%	4.27 x 10 ⁶ (6.63)
		Wash Water Log Reduction	>99.99%	>99.99%	>99.99%	5.73 x 10 ⁶ (6.73)
						3.80 x 10 ⁶ (6.58)
50749708 50749709 50749710	Staphylococcus aureus (ATCC 6538)	1:10 (weight/weight) for Top-loading Applications	99.999%	99.99%	99.999%	1.23 x 10 ⁷ (7.09)
		Wash Water Log Reduction	>99.99%	>99.99%	>99.99%	8.91 x 10 ⁶ (6.95)
						5.13 x 10 ⁶ (6.71)
15-minute 50-second contact time, 100 ppm hard water, no soil load, 1:116.65 dilution ratio						
50749711 50749712 50749713	Klebsiella pneumoniae (ATCC 4352)	1:4.99 (weight/weight) for High Efficiency Applications	99.9%	>99.99%	>99.9%	3.16 x 10 ⁶ (6.50)
		Wash Water Log Reduction	>99.99%	>99.99%	>99.99%	1.07 x 10 ⁶ (6.03)
						3.24 x 10 ⁶ (6.51)
50749714 50749715 50749716	Staphylococcus aureus (ATCC 6538)	1:4.99 (weight/weight) for High Efficiency Applications	99.99%	>99.99%	99.9%	6.67 x 10 ⁶ (6.83)
		Wash Water Log Reduction	>99.9%	>99.9%	>99.99%	4.57 x 10 ⁶ (6.66)
						1.23 x 10 ⁷ (7.09)

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50749705 50749706 50749707 50749708 50749709 50749710	Laundry Sanitizer 1:10 (weight/weight) for Top-loading Applications	Plain cotton weave fabric	7 mL/ 993 mL (ratio 1:141.86)	8 minute 50 second	N/A	100 ppm AOAC synthetic hard water	<ul style="list-style-type: none"> • <i>Klebsiella pneumoniae</i> (ATCC 4352) • <i>Staphylococcus aureus</i> (ATCC 6538) 	Yes
50749711 50749712 50749713 50749714 50749715 50749716	Laundry Sanitizer 1:4.99 (weight/weight) for High Efficiency Applications	Plain cotton weave fabric	8.5 mL /991.5 mL (ratio 1:116.65)	15 minute 50 second	N/A	100 ppm AOAC synthetic hard water	<ul style="list-style-type: none"> • <i>Klebsiella pneumoniae</i> (ATCC 4352) • <i>Staphylococcus aureus</i> (ATCC 6538) 	Yes

VI LABEL COMMENTS

Label Date: 1/4/19

1. The proposed label claims that the product, Tail, EPA Reg. No. 5813-REG, when diluted at 7 mL product per 993 mL (ratio 1:141.86) of water, is an effective Laundry Sanitizer (1:10 (weight/weight) for top loading applications) against the following on plain cotton weave fabric in the presence of no organic soil for a 9-minute contact time:

Klebsiella pneumoniae (ATCC 4352)
Staphylococcus aureus (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Tail, EPA Reg. No. 5813-REG, when diluted at 8.5 mL product per 991.5 mL (ratio 1:116.65) of water, is an effective Laundry Sanitizer (1:4.99 (weight/weight) for High Efficiency Applications) against the following on plain cotton weave fabric in the presence of no organic soil for a 16-minute contact time:

Klebsiella pneumoniae (ATCC 4352)
Staphylococcus aureus (ATCC 6538)

These claims are **acceptable** as they are supported by the submitted data.

Note: In the future it would be helpful to have additional information to justify contact times in excess of 10 minutes. In particular, rinse cycle times for a few different brands of HE machines would be useful.

3. Make the following changes to the proposed label:
 - a. On page 3 of the proposed label, add the product to water ratio (equivalent to testing) to use directions, as machine and setting could vary in water volume.
 - b. On page 4 of the proposed label,
 - i. remove the word “(common)” from the claims “kills 99.9% of (common) bacteria”, as this may be false or misleading to the user.
 - ii. Qualify 2-in-1 in claims with “when used according to the directions for sanitization”
 - iii. Remove the claim “dial down to cold [water], [still] kills [99.9%] of bacteria.” The product was not tested with cold water.
 - iv. Revise the claim “Helps or defends or avoids [your] clothing or clothes from cross-contamination in the washer or washing machine” as follows: Remove “avoids” and “add “between treated materials” after “cross contamination”.
 - v. Include “treated” or “on treated material”, to the claim “kills 99.9% of bacteria to stop transmission from clothing to clothing”. For example, claim may read “kills 99.9% of bacteria to stop transmission from treated clothing to clothing”. In addition, revise “stop” to “reduces”.
 - c. On page 5 of the proposed label, include “treated” or “on treated material”, to the claim “prevents bacteria transfer between sheets” And revise “prevents” to “reduces”. For example, the claim may read, “reduces bacteria transfer between treated materials such as sheets.”.
 - d. Remove all claims of “hygienic” or “hygienically”, as this may be misleading to the user.